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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,684	01/28/2004	Nabil L. Muhanna	126013-1003	2069
7501 L20222008 STEVEN E. ROSS, IP SECTION KENNETH T. EMANUELSON			EXAMINER	
			SNOW, BRUCE EDWARD	
GARDERE WYNNE SEWELL LLP 1601 ELM STREET, SUITE 3000		ART UNIT	PAPER NUMBER	
DALLAS, TX 75201			3738	
			MAIL DATE	DELIVERY MODE
			12/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/766.684 MUHANNA ET AL. Office Action Summary Examiner Art Unit Bruce E. Snow 3738 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 08 September 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 19 and 21-42 is/are pending in the application. 4a) Of the above claim(s) 33 and 37-41 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 29, 21-32, 34-36, 42 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date ______.

5) Notice of Informal Patent Application

6) Other:

Art Unit: 3738

DETAILED ACTION

Response to Arguments

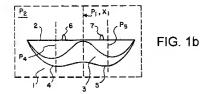
Applicant's arguments filed 9/8/08 have been fully considered. Regarding the rejection under 35 U.S.C. 102(b) as being anticipated by Burkinshaw (6,602,292), Applicant argues that the Burkinshaw prosthetic is used for the patella where it is orientated differently than applicant's device. It is the Examiner's position that this is merely functional use wherein the device of Burkinshaw is <u>sized and configured</u> and fully capable of being used in the disc. MPEP 2114 teaches: A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim.

Regarding the rejection under 35 U.S.C. 102(b) as being anticipated by Giannestras et al (3,872,519), applicant argues that the prosthesis B is a "single groove, double-ridged surface" which is not a "single shape". The Examiner interprets this shape as being a "substantially hyperbolic paraboloid shape". The Examiner further interprets the as entire articulating surface as a single surface. Giannestras et al describes the shape collectively as a single shape. Note that Gainnestras et al description is a "single groove, double-ridged surface" not a "single groove surface and a double-ridged surface".

Regarding the rejection under 35 U.S.C. 102(b) as being anticipated by Shelokov (6,039,763), Shelokov teaches "the articulating surfaces (3,12) can be regularly or

Art Unit: 3738

irregularly shaped as at least partially complementary portions of ..hyperboloids (6:51 et seq.)." The



Surface 3 is interpreted as a "single articulating surface".

hy•per-bo•loid нея (hī-pûr'b□-loid') Pronunciation Key



Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-32, 34-36, and 42 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 3738

Regarding claims 19 and 31, a "single articulating surface has a substantially hyperbolic paraboloid shape" is ambiguous. The specification fails to describe the limitation and one having ordinary skill in the art is unable to determine its boundary. The combination of "single articulating surface" in combination with "substantially hyperbolic .." is unclear; "substantially" can include other surfaces?

Regarding claim 42, "hyperbolic paraboloid shape" is interpreted as being broader than a hyperbolic paraboloid. The ambiguity is how much broader. Again, the specification fails to describe the limitation and one having ordinary skill in the art is unable to determine its boundary when combined with the limitation "single articulating surface".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1993); *In re Goman*, 11 F.3d 14046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 3738

Claims 19, 21-32, 34-36, 42 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 19-36 of copending Application No. 11/648,384. This is a <u>provisional</u> double patenting rejection since the conflicting claims have not in fact been patented.

Claims 19, 21-32, 34-36, 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-36 of copending Application No. 11/648,384. Although the conflicting claims are not identical, they are not patentably distinct from each other because are a broader language for the same device:

(NEW) A prosthetic disc comprising:

a disc body, having a first surface that is a concave-convex articulating surface and a second surface as a base adapted for fixation to a first bone surface.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

Art Unit: 3738

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 19, 21-32, 34-36, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Burkinshaw (6.602.292).

Burkinshaw teaches:

19. (Currently Amended) A prosthetic disc comprising:

a disc body 30 having a first surface 44 that is a concave-convex articulating surface and a second surface 74 as a base adapted for fixation to a first bone surface, wherein the concave-convex articulating surface has a substantially hyperbolic paraboloid shape (see 4:8).

Claim 24, see 34.

Claims 26-28, see 5:48 et seq.

Claim 29 is functional language only.

Art Unit: 3738

Claim 30, fully capable of.

Claim 34 is not positively claiming the second body.

Regarding claim 42, "has a hyperbolic paraboloid shape" is interpreted as being broader and does not limit explicitly to being a hyperbolic paraboloid.

Claims 19, 21-23, 25, 28-32, 34-36, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Giannestras et al (3,872,519).

Giannestras et al teaches:

19. (Currently Amended) A prosthetic disc comprising:

a disc body B, having a first surface (generally 40) that is a concave-convex articulating surface and a second surface (generally 42) as a base adapted for fixation to a first bone surface, wherein the concave-convex articulating surface has a substantially hyperbolic paraboloid shape.

Claim 23, see 3:49.

Claim 34, see element A.

Regarding claim 42, "has a hyperbolic paraboloid shape" is interpreted as being broader and does not limit explicitly to being a hyperbolic paraboloid.

Claims 19, 21-32, 34-36, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Shelokov (6.039.763).

Art Unit: 3738

Shelokov teaches a prosthetic disc comprising:

a first and second disc bodies 1, 10 having complimentary saddle shaped articulating surfaces each surface being one of concave and convex in a first plane and the other of concave and convex in a perpendicular plane to first. The surfaces can be described as being parabolic, hyperbolic, or follows a radius.

The reference clearly teaches a disc body, having a first surface which is concave-convex and a second body which has a reciprocally concave-convex articulating surface.

Figure 1b at least shows at least a concave portion along P1. Figure 1a, shows an orthogonal view which is convex along P2; at least the portion along P1, P2 as shown in figure 1C is interpreted as being "substantially hyperbolic paraboloid shape".

Also see 6:46-60. A portion of a hyperboloid would be "substantially hyperbolic paraboloid shape".

Regarding claims 24-27, see at least 9:47 et seq.

Regarding claim 42, "has a hyperbolic paraboloid shape" is interpreted as being broader and does not limit explicitly to being a hyperbolic paraboloid.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3738

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 3738

/Bruce E Snow/ Primary Examiner, Art Unit 3738